

3/12/99

**510(k) SUMMARY
FOR THE
3D-ANGIO SOFTWARE OPTION**

K984634

Submitted by:

Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, NJ 08830

December 28, 1998

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. Contact Person:

Ms. Malgorzata Stanek
Phone: (732) 321-3950 Fax: (732) 321-4841

2. Device Name and Classification:

Trade Name: 3D-Angio
Classification Name: Accessory to Angiographic X-Ray System
Classification Panel: Radiology
CFR Section: 21 CFR §892.1600
Device Class: Class I.I.
Product Code: 90JAA

3. Substantial Equivalence:

The 3D-Angio software option is designed for three-dimensional evaluation of data acquired with a standard angiographic C-arm devices. The package is substantially equivalent to the following device:

<i>Siemens Device Name</i>	<i>FDA Clearance Number</i>	<i>FDA Clearance Date</i>
GE Advantage 3D XR	K974715	7/6/98

4. Device Description:

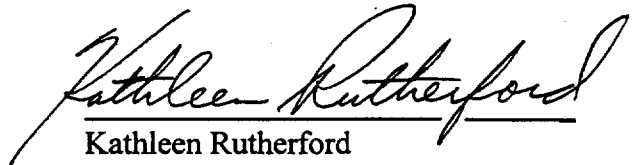
The 3D-Angio package is a x-ray imaging software option which allows the reconstruction of two-dimensional images acquired with a standard angiographic C-arm device into a three-dimensional image format.

5. Intended Use of the Device:

The resulting images of the 3D-Angio package are intended to assist the physician in diagnosis and treatment of vessel malformations (i.e. aneurysms, AVMs, stenoses), particularly neuro-angiographic cases.

6. Summary of Technological Characteristics of the Devices Compared to the Predicate:

Both the Siemens 3D-Angio software option and GE Advantage 3D XR allow construction of a three-dimensional model from images acquired during rotational angiography.

A handwritten signature in black ink, reading "Kathleen Rutherford". The signature is fluid and cursive, with a horizontal line drawn underneath the name.

Kathleen Rutherford
Manager, Regulatory Submissions
Siemens Medical Systems, Inc.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 12 1999

Malgorzata Stanek
Technical Specialist
Siemens Medical Systems, Inc.
186 Wood Ave. South
Iselin, NJ 08830

Re: K984634
3D-Angio (3D Angiographic Accessory)
Dated: December 28, 1998
Received: December 30, 1998
Regulatory class: II
21 CFR 892.1600/Procode: 90 JAA

Dear Ms. Stanek:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K984634
Device Name: 3D-Angio

Indications For Use:

The 3D-Angio package is a x-ray imaging software option which allows the reconstruction of two-dimensional images acquired with a standard angiographic C-arm device into a three-dimensional image format.

The 3D-Angio package is intended to assist the physician in diagnosis and treatment of vessel malformations (i.e. aneurysms, AVMs, stenoses), particularly neuro-angiographic cases.

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

David G. DeGeron
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K984634

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)